DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-154/S-034
NDA 20-155/S-025
NDA 20-156/S-026

Bristol-Myers Squibb Company
Attention: Mari-Laure Papi
Associate, Worldwide Regulatory Affairs
5 Research Parkway
Wallingford, CT 06492

Dear Ms. Papi:

Please refer to your supplemental new drug applications dated July 7, 2000, received July 10, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VIDEX® and (didanosine) Buffered Tablets, VIDEX® (didanosine) Buffered Powder for Oral Solution, VIDEX® (didanosine) Pediatric Powder.

We acknowledge receipt of your submission dated July 7, 2000.

These "Changes Being Effected" supplemental new drug applications provide for new information regarding increased didanosine exposure when didanosine is dosed concomitantly with allopurinol to be incorporated into the VIDEX® package insert, resulting in a new **Drug Interactions**, Allopurinol section, as follows:

> "In 14 healthy volunteers, the mean AUC of didanosine increased approximately 2-fold when a 300-mg dose of allopurinol (daily for 7 days) was given with a single 400- mg dose of VIDEX. Coadministration of didanosine and allopurinol is not recommended."

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted July 7, 2000). Accordingly, these supplemental applications are approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Destry M. Sillivan, M.S., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Debra Birnkrant
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NDA 20-155, NDA 20-154, NDA 20-156